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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/609,053

06/27/2003

Richard A. Gambale

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05/09/2008

Kirkpatrick & Lockhart Preston Gates Ellis LLP
(FORMERLY KIRKPATRICK & LOCKHART NICHOLSON GRAHAM)
STATE STREET FINANCIAL CENTER
One Lincoln Street
BOSTON, MA 02111-2950

EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

05/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|---------------------------------------|--|
| Office Action Summary | Application No. 10/609,053 | Applicant(s) GAMBALE ET AL. | |
| | Examiner CHRISTOPHER D. KOHARSKI | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-16, 19 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-16, 19 and 25-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/25/2008 has been entered.

Response to Amendment

Examiner acknowledges the reply filed 1/25/2008 in which claims 12 were amended and new claims 25-27 were added. Examiner also acknowledges the amended abstract filed 1/25/2008.

Claim Rejections - 35 USC § 112

Claims 25 and 27 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The subject matter of claims 25 and 27 is already disclosed in independent amended claim 1, specifically the limitation "...causing the distal end of the shaft to rotate through an angular displacement...".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-15 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi (USPN5,415,637) in view of Hammerslag et al. (USPN5,372,587). Khosravi discloses a temporary stenting catheter with drug delivery capabilities.

Regarding claims 12-15 and 25-27, Khosravi discloses a catheter-based procedure to a particular treatment site within a patient comprising: providing a catheter (Figures 1-1a) comprising a tubular shaft (10) having a proximal end and a distal end and a radially extendible tissue engagement mechanism (28) at its distal end, the radially extendible tissue engagement mechanism comprising a plurality of resilient members (28) configured to be selectively engaged so that the resilient members extend radially outward from a longitudinal axis (along 7), each having proximal and distal ends, all distal ends joined together (31) and fixed longitudinally relative to the shaft adjacent its distal end and all proximal ends joined together (near 28e) and to the shaft at a position proximal to the distal end such that the resilient members lie parallel and are actuated by a pull wire (13); navigating the catheter so that the distal end is

adjacent to the intended treatment site (for drug delivery); causing the tissue engagement mechanism to extend into engagement with the tissue col 5, ln 10-40) adjacent to the treatment site; and performing the procedure while maintaining the tissue engagement mechanism in its extended position (Figures 1-1a, cols 1-2).

Khosravi meets the claim limitations as described above except for the express limitation of the distal shaft end rotating through an angular displacement.

However, Hammerslag et al. teaches a steerable medical device.

Regarding claims 12-15 and 25-27, Hammerslag et al. teaches a catheter (210, Figures 24-26) with a pull wire (234) that causes the distal end of the shaft to rotate through an angular displacement when a compressive load is applied to pull wire (234) (Figures 24 and 25, cols 1-2).

At the time of the invention, it would have been obvious to operate the catheter of khosravi in the manner described of Hammerslag et al. to allow for distal end steering; both catheters have offset pull wires which would provide distal end motion during actuation of the pull wire. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Hammerslag et al. (cols 1-2).

Claim Rejections - 35 USC § 103

Claims 16 and 19 are rejected under 35 U.S.C 103(a) as being unpatentable over Khosravi (USPN5,415,637) in view of Hammerslag et al. (USPN5,372,587) in further view of Edwards et al. (USPN5,461,982). The modified Khosravi meets the

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claim limitations as described above except for the electrical detection and thermal intervention.

However, Edwards et al. teaches a cardiac mapping and ablation system.

Regarding claims 16 and 19, Edwards et al. teaches a catheter (10) with a distal end (20) with cardiac sensing and thermal electrodes (20) (col 4, ln 25-50).

At the time of the invention, it would have been obvious to add the electrical electrode components of Edwards et al. to the modified system of Khosravi in order to add additional diagnostic functions. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Edwards et al. (cols 1-2).

Response to Arguments

Applicant's arguments with respect to claims 12-16, 19, and 25-27 have been considered but are moot in view of the new ground(s) of rejection.

Suggested Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggests further clarification of the flexible member and catheter fixation points (30, 26) as shown in Applicant's Figure 1.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 05/07/2008

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763